

General Instructions

Table 1 and Table 4

Hard copy consists of two parts: 1) Table 1 - Summary of Accrual for all types of protocols, and 2) Table 4 - CCOP Patient Representation by Sex and Ethnic origin. The floppy disk will also consist of two files for the above data: 1) Table 1, and 2) Table 4.

Please submit Table 1 and Table 4 as two separate text files. These text files should be submitted as an email attachment to ccop@imsweb.com. A text file is a generic data file in ASCII format that is readable by IBM-compatible computers. If you are unclear about the format, please call David Castenson at I.M.S. (301-984-3412 ext.28).

Creating Text Files for Submission (For both Table 1 and Table 4)

If you are using a Word Processing Program such as Microsoft Word or Word Perfect for Windows use *Courier New* font, this will allow the columns to appear in the correct positions on the screen when you are entering the data. One can use *Courier New* font because in this font each character takes up the same amount of space.

Examples:

Times New Roman - (It is hard to tell if the columns are correct)

35412 CALGB CALGB-9605	RX	0001 1.0 0001.0
35412 MDA T96-0009	RX	0001 1.0 0001.0

Courier New - Easy to tell the columns are aligned

35412 CALGB CALGB-9605	RX	0001 1.0 0001.0
35412 MDA T96-0009	RX	0001 1.0 0001.0

Microsoft Word

If you use Microsoft Word to enter data, the column position is shown (i.e. col 1) at the bottom of the screen on the toolbar. When saving the text file, select the correct file format; either .txt text only, or .txt MS DOS text. When closing the document if asked if you want to save the formatting changes; select 'NO' at this prompt.

Word Perfect for Windows

There is not a column location for this software. Please save the document as .txt ASCII DOS Text.

Please do NOT use tabs to ensure correct columns as this will render the file unreadable by our database programs.

General Instructions, continued

Notepad / WordPad

These programs can be found under Programs, then Accessories, if you are using

Windows 95. Also, these programs should be in your c:\windows, c:\win311 , or c:\win95 directories on your hard drive. One can use either of these programs to create the text file, just be sure to save as a text file/document where appropriate.

Alternative methods

Almost all database, spreadsheet, text editor, and word processor systems have the ability to create text files. For example: 1) in LOTUS select '/', 'PRINT', and 'FILE' 2) in WordPerfect for DOS select 'Ctrl-F5' (Text Out) and 'T' (DOS Text) 3) in dBASE use the command "COPY TO filename TYPE SDF". A single text file should contain the data for all the research bases combined rather than a separate file for each research base. Please include your grant number in the name of the text file (i.e. "CA12345.TXT" if your grant number is 12345).

Text File Layout

Each data item (or field) must be in the specified format and within the specified columns (or spaces) in the text file. A space is left between each field so that it is easier to distinguish them. Each alphabetic and alphanumeric data item should be left-justified and space-filled on the right (i.e. 'POG ' rather than ' POG'). Numeric data items should be right-justified and zero-filled on the left (i.e. '0025' rather than '25 ' or ' 25'). See the attached "Text File Format" for the specific columns, format, and codes for each field.

Provide one line for each NCI-approved protocol on which you have entered patients during the designated time period. Additional lines should be included for protocols receiving more than one type of credit (i.e. POG-9233/34 may have both treatment and cancer control credit; NSABP P-1 may have both cancer control and follow-up credit). No titles, blank lines, total lines or any other information should be included in the text file.

General questions about the data and the submission schedule should be addressed to NCI's Division of Cancer Prevention at 301-496-8541 (ask for Cynthia Whitman). Technical questions about the data format and computer issues should be addressed to Information Management Services, Inc. at 301-984-3412 (ask for David Castenson). Attached are: 1) the "Data Item Instructions" containing specific instructions for each data item, 2) the "Text File Format" with the specific columns, format, and codes for each data item, and 3) a listing of an example text file.

Table 1 - Summary of Accrual For All Types of Protocols

Data Item Instructions

CCOP Grant Number - Enter the 5-digit grant number for your CCOP or MBCCOP.

Research Base - Enter the abbreviation for the research base. Please be sure the abbreviation is exactly as listed in the "Text File Format" (i.e. MDA rather

than MDACC).

Protocol Number - Enter the number assigned to the study by NCI (including all punctuation). Do not enter any "local" numbers. Please make sure the number is exactly as listed in the CCOP Research Base Protocol Credit Assignment listing received from NCI. Do not include any protocols that have not yet been approved and/or do not receive credit from NCI.

Intergroup Number - If the study is an intergroup study, enter the intergroup number (if known), otherwise leave this field blank (i.e. if the protocol number is EST-2491 then the intergroup number INT-0129 should be entered).

Type of Credit - Enter the code for the type of credit (treatment, cancer control, or follow-up). Protocols with more than one type of credit should have a separate line entered for each type.

Example:

12345	EST	E1195	RX	0001	1.0	0001.0
12345	EST	E1195	CC	0001	0.5	0000.5
12345	NSABP	NSABP P-2	FU	0001	0.3	0000.3

Number of Participants - Enter the number of participants accrued to the study during the designated time period.

Credits per Entry - Enter the number of credits assigned to the study.

Total Credits - Enter the total number of credits for the designated time period

Example: (Number of participants X credits per entry = total credits)

Table 1 - Summary of Accrual For All Types Of Protocols

Text File Format

<u>Item</u>	<u>Columns</u>	<u>Attributes/Values</u>
CCOP Grant Number	1-5	Numeric
Research Base	7-11	Alphabetic CALGB = Cancer and Acute Leukemia Group B CCG = Children's Cancer Group COG = Children's Oncology Group CTSU = Cancer Trials Support Unit EST = Eastern Cooperative Oncology Group FCCC = Fox Chase Cancer Center GOG = Gynecologic Oncology Group MDA = M. D. Anderson Cancer Center NCCTG = North Central Cancer Treatment Group NSABP = National Surgical Adjuvant Breast and Bowel Project POG = Pediatric Oncology Group RTOG = Radiation Therapy Oncology Group SWOG = Southwest Oncology Group UMCC = University of Michigan Cancer Center URCC = University of Rochester Cancer Center CCCWFU = Comprehensive Cancer Center of Wake Forest University
Protocol Number	13-28	Alphanumeric
Intergroup Number	30-45	Alphanumeric (blank if n/a or unknown)
Type of Credit	47-48	Alphabetic RX = Treatment CC = Cancer Prevention and Control FU = Follow-up
Number of Participants	54-57	Numeric (####)
Credits per Entry	59-61	Numeric (#.#)
Total Credits	63-68	Numeric (####.#)

Table 1 - Summary of Accrual For All Types Of Protocols

Listing of Example Text File*

12345	SWOG	SWOG-9114/9232	INT-0163	CC	0001	0.5	0000.5
12345	SWOG	SWOG-9114/9232	INT-0163	RX	0003	1.5	0004.5
12345	EST	E2397		RX	0005	1.0	0005.0
12345	POG	POG-9233/34		RX	0007	1.0	0007.0
12345	POG	POG-9233/34		CC	0007	0.5	0003.5
12345	NSABP	NSABP P-1		FU	0014	0.3	0004.2

* Titles are not included in the text file. Table 1 text file should contain the data for all the research bases combined rather than a separate file for each research base. Please include your grant number in the name of the text file (i.e. "CA12345.TXT" if your grant number is 12345). The file name for Table 1 file should begin with CA followed by your grant number.

Table 4 - CCOP Participant Representation by Sex and Ethnic Origin

Data Item Instructions

CCOP Grant Number - Enter the 5-digit grant number for your CCOP or MBCCOP.

Research Base - Enter the abbreviation for the research base. Please be sure the abbreviation is exactly as listed in the "Text File Format" (i.e. MDA rather than MDACC).

Protocol Number - Enter the number assigned to the study by NCI (including all punctuation). Do not enter any "local" numbers. Please make sure the number is exactly as listed in the CCOP Research Base Protocol Credit Assignment listing received from NCI. Do not include any protocols that have not yet been approved and/or do not receive credit from NCI.

Sex - Enter the code for the sex of the participant.

Ethnicity - Enter either H for Hispanic or N for Non-Hispanic. This means that you may now have to enter 2 separate lines for each previous line if there are ANY participants considered Hispanic for a given protocol.

Type of Credit - Enter the code for the type of credit (treatment or cancer control). Protocols with more than one type of credit should have a separate line entered for each type.

Example:

```
12345 EST    E1496           M N RX 0000 0000 0000 0004 0000 0000 0000
12345 EST    E1496           F H RX 0000 0000 0000 0001 0000 0000 0000
```

American Indian or Alaskan Native - Enter the number of American Indian or Alaskan Native participants accrued to the study during the designated time period.

Asian - Enter the number of Asian participants accrued to the study during the designated time period.

Native Hawaiian or Pacific Islander - Enter the number of Asian or Pacific Islander participants accrued to the study during the designated time period.

Black - Enter the number of Black, not of Hispanic Origin participants accrued to the study during the designated time period.

White - Enter the number of White, not of Hispanic Origin participants accrued to the study during the designated time period.

More than one race - Enter the number of participants accrued to the study with more than one race during the designated time period.

Unknown - Enter the number of Other or Unknown participants accrued to the study during the designated time period.

Table 4 - CCOP Participant Representation by Sex and Ethnic Origin

Text File Format

<u>Item</u>	<u>Columns</u>	<u>Attributes/Values</u>
CCOP Grant Number	1-5	Numeric

Research Base	7-11	Alphabetic CALGB = Cancer and Acute Leukemia Group B CCG = Children's Cancer Group COG = Children's Oncology Group CTSU = Cancer Trials Support Unit EST = Eastern Cooperative Oncology Group FCCC = Fox Chase Cancer Center GOG = Gynecologic Oncology Group MDA = M. D. Anderson Cancer Center NCCTG = North Central Cancer Treatment Group NSABP = National Surgical Adjuvant Project for Breast and Bowel Cancer POG = Pediatric Oncology Group RTOG = Radiation Therapy Oncology Group SWOG = Southwest Oncology Group UMCC = University of Michigan Cancer Center URCC = University of Rochester Cancer Center CCCWFU= Comprehensive Cancer Center of Wake Forest University
Protocol Number	13-28	Alphanumeric
Sex	30	Alphanumeric M = Male F = Female U = Unknown
Ethnicity	32	Alphanumeric H = Hispanic or Latino N = Not-Hispanic or Latino U = Unknown
Type of Credit	34-35	Alphabetic RX = Treatment CC = Cancer Prevention and Control
American Indian /Alaskan Native	37-40	Numeric (Enter the number of Participants)
Asian	42-45	Numeric (Enter the number of Participants)
Native Hawaiian or Pacific Islander	47-50	Numeric (Enter the number of Participants)
Black or African American	52-55	Numeric (Enter the number of Participants)
White	57-60	Numeric (Enter the number of Participants)
More than one race	62-65	Numeric (Enter the number of Participants)
Unknown or Not Reported	67-70	Numeric (Enter the number of Participants)

Table 4 - CCOP Participant Representation by Sex and Ethnic Origin

Listing of Example Text File*

12345	SWOG	SWOG-9008	M	N	RX	0000	0000	0001	0000	0000	0001	0000
12345	POG	POG-9233/34	F	H	RX	0000	0000	0001	0001	0000	0000	0001
12345	POG	POG-9233/34	M	N	RX	0000	0000	0003	0000	0000	0000	0000
12345	POG	POG-9233/34	M	H	CC	0000	0000	0000	0001	0000	0000	0000

* Titles are not included in the text file. Table 4 text file should contain the data for all the research bases combined. Please include your grant number in the name of the text file (i.e. "SE12345.TXT" if your grant number is 12345). The file name for table 4 should begin with SE followed by your grant number (SE for Sex and Ethnic origin).